

Applicants: Charlotte Hauser-Funke  
Application No. 09/913,631  
Combined Amendment and Response to Restriction Requirement

REMARKS

Applicants reserve the right to prosecute the subject matter of the non-elected claims in a divisional application, if such subject matter is not ultimately granted here.

Claims 50-115 are pending. New claims 99-115 have been added. New claims 106 and 107 comprise the elected species. New claims 114-115 are supported by the specification at page 14, lines 1-14. Amendments have been made to claims 50, 53-56, 60, 62, 65, 70, 72, 75, 77-78, 83-87, 91, 93 and 97 to place them in better patent practice format and for sake of clarity. Support for the amendments to claims 50 and 83 are found in the specification at page 14, lines 1-9. Subject matter contained in the "preferably" clauses is in new claims 99-113. Changes that have been made to the claims are presented above using strikethrough and underlining. It is believed that no new matter has been added.

Applicants elect with traverse to prosecute the invention of Group II, comprising claims 71-76, and the species of Factor VIII which comprises claims 106 and 107.

Regarding the traversal, the basis for the Examiner's restriction is under PCT Rule 13.1 for lack of Unity of Invention. The Examiner alleges that Groups I - III do not form a single inventive concept within Rule 13.2. According to PCT Administrative Rules (Annex B, Part I) "unity of invention exists only when there is a special technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features." The expression "special technical features" is defined in Rule 13.2 as meaning those technical features that define a contribution which

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each of the inventions, considered as a whole, makes over the prior art.

Applicants refer the Examiner to Annex B in the MPEP entitled "Examples Concerning Unity of Invention", wherein numerous examples are provided to show unity of invention and the recited special technical feature in each example. Thus, by way of illustration, Example 6 in Annex B shows product, process and apparatus claims which share the "special technical feature common to all the claims is the tangential fuel inlets". The Examiner found, at the bottom of page 2 of the Office Action, the special technical feature shared by Groups I and II is "a nucleic acid construct comprising an HRE and a transgene that are not functionally linked." The Examiner does not indicate Group III's relationship to the alleged "special technical feature". In the instant case, Applicants submit that the special technical feature shared by all of the claims in Groups I - III is the nucleic acid construct comprising at least one HRE and a transgene. Because the claims are directed to a nucleic acid construct, a method of preparing an agent for gene transfer using the nucleic acid construct, and a method of preparing an agent for treating hemophilia using the nucleic acid construct, they all share this special technical feature and thus unity of invention exists. Accordingly, Applicants submit the restriction is improper and request the restriction requirement to be withdrawn.

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Early and favorable action is earnestly solicited.

Respectfully submitted,

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